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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/573,882 | 07/19/2006 | Lutz F. Schweiger | 088736-0113 | 9918 |
| 22428 | 7590 | 03/23/2009 | EXAMINER | |
| FOLEY AND LARDNER LLP | | | MCDOWELL, BRIAN E | |
| SUITE 500 | | | | |
| 3000 K STREET NW | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20007 | | | 1624 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/23/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/573,882 | SCHWEIGER ET AL. | |
| | Examiner | Art Unit | |
| | BRIAN McDOWELL | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 February 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 63-125 is/are pending in the application.
- 4a) Of the above claim(s) 115-125 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 63-114 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/29/2006, 9/26/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

/BEM/

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and election of specie in the reply filed on 2/25/2009 is acknowledged. However, the election of specie requirement is removed. Claims 115-125 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely **traversed** the restriction (election) requirement in the reply filed on 2/25/2009. The traversal is on the ground(s) that there would be no undue search burden to the examiner. This is not found persuasive because the inventions were shown to lack a special technical feature as evidenced in the previous office action, thus restriction is proper. The seven inventions cover a myriad of topics and contain different subject matter, thus a search of one invention would not necessarily cover the subject matter of another.

The requirement is still deemed proper and is therefore made **FINAL**.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on 2/25/2009. A complete reply to this action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

An action of the merits of claims 1 and 63-114 is contained herein.

Priority

This application receives the foreign priority date of 9/29/2003, drawn to foreign priority document GB 0322756.8.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 63-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant claim 1, applicant recites the limitation “or a phenothiazine-like compound”. The examiner can not interpret the metes and bounds of this limitation in the claim. What compounds are supposed to be embraced by a “phenothiazine-like compound”? Since claims 63-114 depend on claim 1, and fail to provide clarity on this issue, these claims are rejected as well.

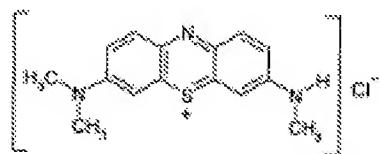
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 63-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagren *et al.* (J.Labelled Cmp. Radiopharm) in view of Link *et al.* (European Journal of Nuclear Medicine)-both references mentioned in IDS.

The instant claims are drawn to a method of [¹¹C]-radiolabelling the following phenothiazine compound:



with [¹¹C]methyl trifluoromethanesulfonate, also known as [¹¹C]methyl triflate, under standard conditions. The compound may be used for PET imaging and treating skin cancer such as melanoma.

Nagren *et al.* teach that commonly used labeled precursors in the preparation of ^{11}C -radiopharmaceuticals for PET include $[^{11}\text{C}]\text{-methyl iodide}$ and $[^{11}\text{C}]\text{methyl triflate}$ (see page 832, first paragraph). In particular, this document cites that the preparation of PET radioligands by *N*-methylation of amines is performed using mild conditions (e.g., methylation of the free base using a mild base, see page 837, third paragraph) to afford high yields of the desired radioactive compound.

However, this document does not explicitly teach $[^{11}\text{C}]$ -radiolabelling the phenothiazine compound above.

Link *et al.* teach that radioderivatives of methylene blue (compound shown above) may be used for both diagnosis and therapy of melanoma (see abstract of document).

Therefore, one of ordinary skill would have been motivated at the time the invention was made to develop a method for $[^{11}\text{C}]$ -radiolabelling methylene blue employing either one of the $[^{11}\text{C}]$ -radiolabelling reagents described by Nagren and subsequently use this compound for PET or treating melanoma. The claimed purification methods are routine practices of purification in the field of synthetic chemistry and specific reaction times would fall under routine experimentation and are not considered novel.

“Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955)

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN McDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian. E. McDowell./
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner AU 1624